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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,280	06/15/2001	Todd A. Thompson	9345.17121-CON 2	8625

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EXAMINER

SMITH, RUTH S

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/882,280	Applicant(s) THOMPSON ET AL.	
	Examiner Ruth S. Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,8,9 and 26-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,8,9 and 26-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/12/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 12, 2005 has been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26-30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 26 defines the halter assembly as being worn on the patient and including components worn about the shoulders and back of the patient thereby including the patient as part of the claimed invention. The inclusion of a living being as part of the claimed invention renders the claim non-statutory.

Claim Objections

Claims 31-37 are objected to because of the following informalities: In claim 31, line 12, "applicator" (second occurrence) is misspelled. In claim 35-37, it is confusing to set forth an ECG device as a type of treatment device in that it is a diagnostic tool and performs no treatment. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26,30 are rejected under 35 U.S.C. 102(e) as being anticipated by Talish et al ('070). The claims are directly readable on Talish et al which discloses a system for applying ultrasound to the thoracic cavity of a patient comprising an electric signal generating machine 12, an ultrasound applicator 16, and an assembly for placing the applicator on the patient. As seen in figure 1, the assembly can include a halter worn about the back and shoulders. The electrical signal generating machine is battery powered in that the device 12 is disclosed as being the same structure as that used in US Patent No. 5,556,372 which discloses use of a battery 32. The halter assembly includes components that are worn about the back that leave the chest on opposing sides of the applicator uncovered which would allow placement of another treatment device on the chest. The application of ultrasound would inherently result in the increase of blood flow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3,4,9,27-28,31-32,34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talish et al. Talish et al disclose a system for applying ultrasound to the thoracic cavity of a patient comprising an electric signal generating machine 12, an ultrasound applicator 16, and an assembly for placing the applicator on the patient. The assembly includes a quick release mechanism as seen at the end of straps 20 in figure 1 and a quick release material as seen by the Velcro in figure 5. As seen in figure 1, the assembly can include a halter worn about the chest and shoulders. The electrical signal generating machine is battery powered in that the device 12 is disclosed as being the same structure as that used in US Patent No. 5,556,372 which discloses use of a battery 32. The application of ultrasound would inherently result in the increase of blood flow. Talish et al disclose, in column 9, that various modifications can be made to the structural configuration of the placement module. The placement module includes components that are worn about the back that leave the chest on opposing sides of the housing uncovered which would allow placement of another treatment device on the chest. Therefore, in the absence of any showing of criticality, the specific arrangement of the assembly to provide stabilization of the housing would have been an obvious design choice of known functional equivalents in the art, particularly in view of Talish et al disclosing that various modifications can be made to the structural configuration of the placement module. With respect to claim 4, in the absence of any showing of criticality, the specific type of material selected would have been obvious based upon suitability for intended use.

Claims 8,29,33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talish et al ('070) as applied to claims 1,26,31 above, and further in view of Peterson et al. Talish et al fails to specifically disclose the operating parameters of the ultrasound energy. Peterson et al is just one example of many which disclose the operating parameters of the therapeutic ultrasound as set forth in the claims. It would have been

obvious to one skilled in the art to have further modified Talish et al such that the operating parameters are as taught by Peterson et al in that such are well known operating parameters for therapeutic ultrasound which will not cause harm to the patient.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Talish et al ('070) in view of Kullok et al. Talish et al discloses a system for applying ultrasound to the thoracic cavity of a patient comprising an electric signal generating machine 12, an ultrasound applicator 16, and an assembly for placing the applicator on the patient. As seen in figure 1, the assembly can include a halter worn about the back and shoulders. The electrical signal generating machine is battery powered in that the device 12 is disclosed as being the same structure as that used in US Patent No. 5,556,372 which discloses use of a battery 32. The halter assembly includes components that are worn about the back that leave the chest on opposing sides of the applicator uncovered which would allow placement of another treatment device on the chest. The application of ultrasound would inherently result in the increase of blood flow. Talish et al fails to disclose the use of an ECG device. Kullok et al disclose that sympathetic stimulation can have effects on the heart rate and the use of an EKG monitor allows one to monitor the effect of the stimulation. Therefore, it would have been obvious to one skilled in the art to have modified Talish et al such that it includes an ECG device to ensure that the treatment effect is properly monitored.

Claims 35,37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talish et al as applied to claims 1,31 above, and further in view of Kullok et al. Talish et al fails to disclose the use of an ECG device. Kullok et al disclose that sympathetic stimulation can have effects on the heart rate and the use of an EKG monitor allows one to monitor the effect of the stimulation. Therefore, it would have been obvious to one skilled in the art to have modified Talish et al such that it includes an ECG device to ensure that the treatment effect is properly monitored.

Response to Arguments

Applicant's arguments filed 9/12/05 have been fully considered but they are not persuasive. Claims 26-30 positively set forth the halter assembly as being worn about the shoulders of the patient, thereby including the patient as part of the claimed invention. Applicant should set forth that the assembly is "adapted" to be worn about the shoulders of the patient thereby clearly setting forth only the intended use of the device. In claim 31, line 12, "applicator" (second occurrence) is misspelled. With respect to the rejection of claims under 35 USC 103, it is respectfully submitted that the application of ultrasound will inherently result in an increase of blood flow.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S. Smith
Primary Examiner
Art Unit 3737